

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	MDL No. 1456
LITIGATION)	
)	CIVIL ACTION: 01-CV-12257-PBS
)	
)	Judge Patti B. Saris
)	
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THIS DOCUMENT RELATES TO)	
<i>State of Montana v. American Home</i>)	
<i>Products Corp., et al.,</i>)	
D. Mont. Cause No. CV- 02-09-H-DWM)	
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**BAYER CORPORATION'S ANSWER TO
THE STATE OF MONTANA'S SECOND AMENDED COMPLAINT**

Defendant Bayer Corporation ("Bayer"), for its Answer to the State of Montana's Second Amended Complaint (the "Complaint"), states as follows:

Preliminary Statement

The Complaint improperly refers to "drugs" or "pharmaceuticals" on a collective basis. The failure to specifically identify the drugs implicated in each allegation is fatal to the Complaint as to Bayer, for Judge Saris' June 10, 2004 Memorandum and Order (the "6/10/04 Order") "dismiss[ed] all fraud claims concerning drugs covered by the 2001 and 2003 settlements between Montana and Bayer, even those brought in a parens patriae capacity..." See 6/10/04 Order at 15. The 6/10/04 Order bars all of the State's claims against Bayer pertaining to medicines covered by these settlements. To the extent the allegations that pertain to Bayer refer

to medicines dismissed as part of the 6/10/04 Order, Bayer denies those allegations as, among other things, moot.

The Complaint improperly and repetitively refers to Bayer and certain other defendants and third parties on a collective basis, failing to plead with the requisite particularity allegations against Bayer. Intentionally ambiguous pleading is improper and insufficient to apprise Bayer in any meaningful sense of the allegations asserted against it. Bayer has nevertheless attempted to respond to the State's allegations to the extent possible under the circumstances. To the extent allegations refer to the knowledge, conduct, or actions of other defendants or entities, Bayer is without knowledge or information sufficient to form a belief as to the truth of those allegations and, on that basis, Bayer denies those allegations. Bayer states that it is answering the State's allegations on behalf of itself only, even when the State's allegations refer to alleged conduct by Bayer and other persons or entities.

The Complaint improperly mixes factual allegations with inflammatory rhetoric so as to make it virtually impossible to respond meaningfully. Many of the allegations of the Complaint are vague or conclusory. The Complaint also includes terms which are undefined and which are susceptible of different meanings.

The Complaint also contains purported quotations from a number of sources, many of which are unidentified. If any of the quotations originate in documents protected by the attorney-client privilege, the work-product doctrine, or the joint-defense privilege, Bayer reserves the right to assert such privileges, hereby moves to strike such references, and demands return of any such documents that the State may have in its possession, custody, or control. In answering allegations consisting of quotations, an admission that the material quoted was

contained in a document or was uttered by the person or entity quoted shall not constitute an admission that the substantive content of the quote is or is not true or that the material is relevant or admissible in this action.

Bayer denies each and every allegation contained in the Complaint, except as specifically herein admitted, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendoes, or speculations which are contained in any averment or in the Complaint as a whole. Moreover, Bayer specifically denies any allegations contained in headings, footnotes, the Table of Contents, or unnumbered Paragraphs in the Complaint.

These comments and objections are incorporated, to the extent appropriate, into each numbered Paragraph of this Answer.

SECTION ONE

1. Bayer admits that the State of Montana, through Attorney General Mike McGrath (collectively, “the State”), purports to bring this action as alleged but denies that the State is entitled to maintain it. Bayer denies the remaining allegations.

2. To the extent the allegations are directed to other defendants, they require no response from Bayer. Bayer admits that at times it or its affiliates have been engaged in the business of manufacturing, marketing and selling prescription pharmaceuticals throughout the United States, including Montana. Bayer admits that federal and/or state governments, private insurers, self-insured employers, and private individuals may be payors for prescription pharmaceuticals originally manufactured or sold by Bayer. To the extent the allegations of this

Paragraph refer to statutory or regulatory programs, the statutes, regulations and other sources regarding those programs are the best evidence of their content, and any characterizations thereof are denied. Bayer denies the remaining allegations.

3. The allegations set forth in Paragraph 3 contain generalized self-serving claims and conclusions concerning the benefits of prescription drugs for which no answer is required. Bayer answers further that the allegations are vague and ambiguous and thus require no answer. To the extent an answer is deemed to be required, the allegations are denied.

4. The allegations set forth in Paragraph 4 contain generalized self-serving claims and conclusions concerning the market for prescription drugs for which no answer is required. Bayer answers further that the allegations are vague and ambiguous and thus require no answer. To the extent an answer is deemed to be required, Bayer denies the allegations.

5. Bayer admits that Congress has mandated that Medicare Part B reimbursements be based, in part, upon AWP. Bayer further admits that independently produced pricing publications periodically report AWP's for prescription medicines sold in the United States. Bayer states that the publications by First DataBank, Red Book, Blue Book, or Medispan are the best evidence of their contents. Bayer denies the remaining allegations.

6-10. To the extent that the allegations refer to parties or entities other than Bayer, Bayer is without knowledge or information sufficient to form a belief as to their truth or falsity and therefore denies the allegations. Bayer denies the remaining allegations.

11. Bayer admits that certain pharmaceutical manufacturers participating in state Medicaid programs enter into certain rebate agreements with the Secretary of Health and Human

Services. The remaining allegations of this Paragraph constitute conclusions of law and purport to quote from statutes or regulations, to which no response is required. Bayer denies the remaining allegations.

12. To the extent that the allegations refer to parties or entities other than Bayer, Bayer is without knowledge or information sufficient to form a belief as to their truth or falsity and therefore denies the allegations. Bayer denies the remaining allegations.

13-17. Bayer denies the allegations set forth in Paragraphs 13-17.

18. Bayer admits that the State purports to bring this action as alleged but denies that the State is entitled to a judgment or relief against Bayer. Bayer denies the remaining allegations.

19 – 20. Bayer denies the allegations set forth in Paragraphs 19-20.

21 – 23. Bayer admits that the State purports to bring this action as alleged but denies that the State is entitled to a judgment or relief against Bayer. Bayer denies the remaining allegations.

SECTION TWO

24. Bayer admits that the State purports to bring this action as alleged but denies that the State is entitled to a judgment or relief against Bayer. Bayer denies the remaining allegations.

25 – 28. Upon information and belief, Bayer admits that the State of Montana administers a state Medicaid program. The state Medicaid program and Title XIX as referred to

in Paragraph 25 of the Complaint are the best evidence of their contents. To the extent the allegations state legal arguments or conclusions, no answer is required. Bayer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations and therefore denies them.

29. To the extent the allegations state legal arguments or conclusions or are directed to other defendants than Bayer, no answer is required. Bayer denies the remaining allegations.

30. To the extent the allegations are directed to other defendants than Bayer, no answer is required. Bayer admits that at times relevant to this litigation, it or its affiliates transacted business in the State of Montana.

31 – 49. The allegations in Paragraphs 31-49 are directed to other defendants and require no response from Bayer. To the extent the allegations are deemed to pertain to Bayer, they are denied.

50. Bayer admits it is an Indiana corporation with its principal place of business located at 100 Bayer Road, Crafton, Pennsylvania. Bayer admits that it is affiliated with Bayer AG, a management holding company located in Germany. Bayer further admits that its pharmaceutical affiliate is located at 400 Morgan Lane, West Haven, Connecticut. Bayer denies the remaining allegations.

51. Bayer admits that at times relevant to this litigation it was a diversified health care company whose business included the development, manufacture, marketing, sale, and/or

distribution of healthcare products and services, including pharmaceuticals. Bayer denies the remaining allegations.

52. Upon information and belief, Bayer admits that it manufactures certain drugs that ultimately have been purchased by certain citizens in Montana who have been reimbursed by the Montana Medicaid Program.

53 – 111. The allegations in Paragraphs 53-111 are directed to other defendants and require no response from Bayer. To the extent the allegations are deemed to pertain to Bayer, they are denied.

SECTION THREE

112. The allegations set forth in Paragraph 112 contain generalized self-serving claims and conclusions concerning the market for prescription drugs for which no answer is required. To the extent an answer is deemed to be required, Bayer denies the allegations.

113 – 121. Bayer denies that the State has accurately characterized any alleged finding, opinion, statement or conclusion purportedly attributed to the “Chartbook” or other documents referred to in these Paragraphs, or that such are applicable to Bayer. The “Chartbook” and other cited documents are the best evidence of their contents. To the extent the allegations are deemed to pertain to Bayer, they are denied.

122. Bayer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 122 and therefore denies those allegations

123. Bayer denies the allegations in Paragraph 123.

SECTION FOUR

124. The allegations in Paragraph 124 are introductory in nature, without any allegations pertaining Bayer, and thus no answer is required.

125 – 127. The allegations set forth in Paragraph 125 contain the State's general self-serving conclusions and generalizations regarding the prescription drug market without any factual allegations averred against Bayer. Accordingly, no answer is required. To the extent an answer is deemed to be required, the allegations are denied.

128. The allegations set forth in Paragraph 128 contain the State's self-serving conclusions and generalizations regarding the prescription drug market without any factual allegations averred against Bayer. Accordingly, no answer is required. To the extent an answer is deemed to be required, the allegations are denied.

129. The allegations set forth in Paragraph 129 contain the State's general self-serving conclusions and generalizations regarding the prescription drug market without any factual allegations averred against Bayer. Accordingly, no answer is required. To the extent an answer is deemed to be required, the allegations are denied.

130. Bayer admits that AmeriSource-Bergen, McKesson and Cardinal Health are drug wholesalers. The remaining allegations set forth in Paragraph 130 contain the State's general self-serving conclusions and generalizations regarding the prescription drug market without any factual allegations averred against Bayer. Accordingly, no answer is required. To the extent an answer is deemed to be required, Bayer is without knowledge or information sufficient to form a belief as to their truth or falsity and therefore denies those allegations.

131. The allegations set forth in Paragraph 131 contain the State's general self-serving conclusions and generalizations regarding the prescription drug market without any factual allegations averred against Bayer and thus no answer is required. In addition, the allegations set forth in Paragraph 131 state legal arguments or conclusions to which no answer is required.

132. The allegations set forth in Paragraphs 132 contain the State's general self-serving conclusions and generalizations regarding the prescription drug market without any factual allegations averred against Bayer. Accordingly, no answer is required. To the extent an answer is deemed to be required, Bayer is without knowledge or information sufficient to form a belief as to their truth or falsity and therefore denies those allegations.

133. Bayer denies that the State has accurately characterized any alleged finding, opinion, statement or conclusion purportedly attributed to the "Chartbook" referred to in these Paragraphs, or that such are applicable to Bayer. The "Chartbook" is the best evidence of its contents. Bayer denies the remaining allegations.

134. The allegations set forth in Paragraph 134 contain the State's general self-serving conclusions and generalizations regarding the prescription drug market without any factual allegations averred against Bayer and thus no answer is required.

135. The allegations set forth in Paragraph 135 contain the State's general self-serving conclusions and generalizations regarding the prescription drug market without any factual allegations averred against Bayer and thus no answer is required.

136 – 138. The allegations contained in Paragraphs 136-138 relate to entities other than Bayer, and Bayer is without knowledge or information sufficient to form a belief as to their truth or falsity of these allegations. Bayer therefore denies those allegations.

139. Bayer denies that the State has accurately characterized any alleged finding, opinion, statement or conclusion purportedly attributed to the “Chartbook” referred to in these Paragraphs, or that such are applicable to Bayer. The “Chartbook” is the best evidence of its contents. Bayer denies the remaining allegations.

140. The allegations set forth in Paragraph 140 contain the State’s general self-serving conclusions and generalizations regarding the prescription drug market without any factual allegations averred against Bayer and thus no answer is required.

141. The allegations set forth in Paragraph 141 contain the State’s general self-serving conclusions and generalizations regarding the prescription drug market without any factual allegations averred against Bayer and thus no answer is required. In addition, Bayer is without knowledge or information sufficient to form a belief as to their truth or falsity and therefore denies these allegations.

SECTION FIVE

142 – 144. The allegations set forth in Paragraph 142-144 contain the State’s general self-serving legal conclusions without any factual allegations averred against Bayer and thus no answer is required.

145. The allegations set forth in Paragraph 145 contain the State's general self-serving legal conclusions without any factual allegations averred against Bayer and thus no answer is required.

146. The allegations contained in Paragraph 146 state legal arguments or conclusions to which no answer is required. Bayer admits that the reimbursement methodology for drugs covered by Medicare Part B is set forth in part at 42 C.F.R. § 405.517, which is the best evidence of its contents.

147. The allegations set forth in Paragraph 147 contain the State's general self-serving legal conclusions without any factual allegations averred against Bayer and thus no answer is required.

148. The allegations set forth in Paragraph 148 contain the State's general self-serving legal conclusions without any factual allegations averred against Bayer and thus no answer is required.

149. Bayer states that the Program Memo AB-99-63 cited in Paragraph 149 is the best evidence of its contents. Bayer answers further that the allegations set forth in Paragraph 149 contain the State's general self-serving legal conclusions without any factual allegations averred against Bayer and thus no answer is required.

150. Bayer states that the Program Memo AB-99-63 cited in Paragraph 150 is the best evidence of its contents.

151. Bayer admits that there are no government regulations describing how AWP's are calculated, nor any other statutory or regulatory definitions or descriptions of AWP's.

Bayer admits that at times relevant to this litigation it or its affiliates reported certain pricing information for medicines to independently produced pricing publications. To the extent the allegations in Paragraph 151 refer to the knowledge conduct or actions of or benefits received by persons, entities or defendants other than Bayer, Bayer lacks information or knowledge sufficient to form a belief as to the truth or falsity of those allegations and therefore denies them.

152. – 153. The allegations set forth in Paragraphs 152-153 contain the State's general self-serving conclusions and generalizations regarding the prescription drug market without any factual allegations averred against Bayer and thus no answer is required.

154 – 156. Bayer states that the "Medicaid and Prescription Drugs" document cited in Paragraphs 154-156 is the best evidence of its contents. Bayer lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations and therefore denies them.

157. Bayer states that the Kaiser Commission document cited in Paragraph 157 is the best evidence of its contents. Bayer lacks information or knowledge sufficient to form a belief as to the truth or falsity of the second sentence of Paragraph 157, and therefore denies that sentence.

158. The allegations set forth in Paragraph 158 contain the State's general self-serving legal conclusions and generalizations without any factual allegations averred against Bayer and thus no answer is required.

159. The allegations set forth in Paragraph 159 state legal arguments or conclusions to which no response is required. Bayer states further that 42 C.F.R. § 440.120 is the best evidence of its contents. Bayer denies the remaining allegations.

160. Bayer states that the “Detailed Case Studies” cited in Paragraph 160 are the best evidence of their contents. To the extent that the remaining allegations refer to parties or entities other than Bayer, Bayer lacks knowledge or information sufficient to form a belief as to their truth or falsity and therefore denies those allegations.

161. Bayer lacks knowledge or information sufficient to form a belief as to their truth or falsity of the allegations contained in Paragraph 161 and therefore denies the allegations.

162. Bayer states that Mont. Admin. R. 37.86.1105, Mont. Admin. R. 37.86.1101 subsections (1) and (3), and 42 C.F.R. 447.331-32, and the Montana Department of Public Health and Human Services document cited in Paragraph 162 are the best evidence of their contents. Bayer answers further that the allegations set forth in Paragraph 162 contain the State’s general legal conclusions and generalizations without any factual allegations averred against Bayer and thus no answer is required.

163. The allegations set forth in Paragraph 163 state legal arguments or conclusions to which no response is required.

SECTION SIX

164. The allegations set forth in Paragraph 164 are vague and ambiguous and thus require no answer. Bayer answers further that the allegations state legal arguments or conclusions to which no response is required.

165. Bayer lacks knowledge or information sufficient to form a belief as to their truth or falsity of the allegations contained in the first and third sentences of Paragraph 165 and therefore denies the allegations. The second sentence of Paragraph 165 contains general self-serving conclusions and generalizations regarding the prescription drug market without any factual allegations averred against Bayer and thus no answer is required.

166 – 167. Bayer admits that Congress has mandated that Medicare reimbursements be based, in part, upon AWP. Bayer further admits that independently produced pricing publications periodically report AWPs for prescription medicines sold in the United States. Bayer states that the Publishers' publications cited in Paragraph 167 are the best evidence of their contents. To the extent the allegations in Paragraph 166 or 167 refer to parties or entities other than Bayer, Bayer lacks knowledge or information sufficient to form a belief as to their truth or falsity and therefore denies those allegations. Bayer denies the remaining allegations.

168. Bayer states that the publications and pleadings cited in Paragraph 168 are the best evidence of their contents. To the extent the allegations in Paragraph 168 refer to parties or entities other than Bayer, Bayer lacks knowledge or information sufficient to form a belief as to their truth or falsity and therefore denies those allegations. Bayer denies the remaining allegations.

169. The first sentence of Paragraph 169 is argumentative, vague, and ambiguous, and thus no answer is required. Bayer denies the remaining allegations set forth in Paragraph 169.

170 – 171. Bayer denies that the State has accurately characterized any alleged OIG finding, opinion, statement or conclusion, or that such are applicable to Bayer. Bayer states that the April 2003 OIG report cited in Paragraphs 170 and 171 is the best evidence of its contents.

172. Bayer denies the allegations contained in Paragraph 172.

SECTION SEVEN

173. Bayer denies the allegations contained in Paragraph 173.

174. Bayer denies the allegations contained in Paragraph 174.

175. Bayer denies the allegations contained in Paragraph 175.

176. Bayer admits that at times relevant to this litigation it or its affiliates have reported certain pricing information for medicines to independently produced pricing publications. To the extent the allegations refer to parties or entities other than Bayer, Bayer lacks knowledge or information sufficient to form a belief as to their truth or falsity and therefore denies the allegations. Bayer denies the remaining allegations.

177-184. Bayer denies the allegations contained in Paragraphs 177-184.

185 – 200. The allegations set forth in Paragraphs 185 through 200 are directed at other defendants and no response from Bayer is required. To the extent an answer is deemed to be required, Bayer denies these allegations.

201 – 207. The allegations set forth in Paragraphs 201-207 concern entities other than Bayer, and Bayer is without knowledge or information sufficient to form a belief as to their truth or falsity, and therefore denies these allegations.

208. Bayer denies the allegations contained in Paragraph 208.

209. The allegations set forth in Paragraph 209 concern entities other than Bayer, and Bayer is without knowledge or information sufficient to form a belief as to their truth or falsity, and therefore denies these allegations

210. Bayer admits that the DOJ and the OIG have previously investigated Bayer, among others, for practices relating to AWP. Bayer denies the remaining allegations.

211 – 212. Bayer denies that the State has accurately characterized the findings, opinions, statements or conclusions of Congressman Stark cited in Paragraph 211 through 212, or that such are applicable to Bayer. Bayer states that the September 28, 2000 letter from Congressman Stark to the President of Pharmaceutical Research and Manufacturers of America is the best evidence of its contents.

213. Bayer is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 213 and therefore denies the allegations.

214. Bayer denies the allegations set forth in Paragraph 214.

215. Bayer admits that the State purports to charge Defendants as alleged, but denies that the State is entitled to a judgment or any relief.

216 – 312. The allegations in Paragraphs 216 through 312 are directed to other defendants and require no response from Bayer. To the extent the allegations are deemed to pertain to Bayer, they are denied.

313. Bayer denies the allegations set forth in Paragraph 313.

314. Bayer admits that the State purports to bring this action as alleged but denies that the State is entitled to a judgment or any relief. Bayer denies the remaining allegations.

315. Bayer admits that it produced the document cited in Paragraph 315 (BAY005278), but states that the document is the best evidence of its contents and denies that the conclusions the State draws from the document are accurate. Bayer denies the remaining allegations.

316. Bayer denies the allegations set forth in Paragraph 316.

317. Bayer denies that it produced the document cited in Paragraph 317 (P007549) and states that the September 28, 2000 letter from Representative Stark to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, is the best evidence of its contents. Bayer denies that the conclusions drawn by the State are accurate. Bayer denies the remaining allegations.

318. Bayer states that the September 25, 2000 letter from Tom Bliley to the Health Care Financing Administration cited in Paragraph 318 is the best evidence of its contents.

319. Bayer admits that at various times relevant to this litigation it or its affiliates have sold certain medicines at prices lower than the published AWP for those medicines. Bayer denies the remaining allegations set forth in Paragraph 319.

320. Bayer denies the allegations set forth in Paragraph 320.

321. Bayer denies that it produced the document cited in Paragraph 321 and states that the purported October 1, 1996 memorandum is the best evidence of its contents. Bayer denies that the State has accurately characterized any alleged document, finding, opinion, statement, or conclusion.

322 – 323. Bayer denies the allegations set forth in Paragraphs 322-323.

324. The allegations in Paragraph 324 concern matters that have been dismissed pursuant to the 6/10/04 Order and thus require no answer.

325. Bayer denies the allegations contained in Paragraph 325.

326. Bayer states that the settlement of government claims and the corporate integrity agreement cited in Paragraph 326 are the best evidence of their contents. Bayer denies the allegations to the extent they are inconsistent with the settlement or the corporate integrity agreement.

327. The allegations in Paragraph 327 concern matters that have been dismissed pursuant to the 6/10/04 Order and thus require no answer.

328 – 329. The allegations in Paragraphs 328-329 concern matters that have been dismissed pursuant to the 6/10/04 Order and thus require no answer.

330. The allegations in Paragraph 330 concern matters that have been dismissed pursuant to the 6/10/04 Order and thus require no answer.

331. Bayer denies the allegations set forth in Paragraph 331.

332 – 602. The allegations in Paragraphs 332 through 602 are directed to other defendants and require no response from Bayer. To the extent the allegations are deemed to pertain to Bayer, they are denied.

SECTION EIGHT

603 – 634. The State's "Best Price" claims set forth in Paragraphs 603-634 have been dismissed pursuant to the 6/10/04 Order as against Bayer and thus no response is required. To the extent a response is deemed required, these allegations are denied.

SECTION NINE

635. Bayer denies the allegations set forth in Paragraph 635.

636. Bayer states that the 2003 CMS document cited in Paragraph 636 is the best evidence of its contents. Bayer denies that the State has accurately characterized any alleged CMS finding, opinion, statement, or conclusion. Bayer admits that at times relevant to this litigation it or its affiliates sold medicines in a competitive market and, as such, took steps to protect against unauthorized disclosure certain pricing and marketing plans related to their medicines. Bayer denies the remaining allegations.

637 – 641. Bayer denies the allegations set forth in Paragraphs 637 through 641.

642 – 643. The allegations set forth in Paragraphs 642-643 state legal arguments or conclusions to which no response is required.

SECTION TEN

644. Bayer denies that the State has suffered damages or injuries as alleged in Paragraph 644 of the Complaint. Bayer lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 644 of the Complaint and therefore denies those allegations.

645. The allegations set forth in Paragraph 645 state legal arguments or conclusions to which no answer is required.

646. Bayer denies the allegations in Paragraph 646.

647. The allegations in Paragraph 647 are directed to other defendants and require no response from Bayer. To the extent the allegations are deemed to pertain to Bayer, they are denied.

648. Bayer denies the allegations in Paragraph 648.

649. Bayer is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in the first sentence of Paragraph 649 and therefore denies the allegations. Bayer denies the remaining allegations.

650. Bayer denies the allegations in Paragraph 650.

651. Bayer denies the allegations in Paragraph 651.

652. Bayer denies the allegations in Paragraph 652.

653. Bayer is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in the first sentence of Paragraph 653 and therefore denies the allegations. Bayer denies the remaining allegations.

SECTION ELEVEN

COUNT I

654. Bayer realleges and incorporates its responses to the allegations in Paragraphs 1 through 653.

655. Bayer admits that the State purports to bring this action and to seek relief under Count I as alleged but denies that the State is entitled to maintain this action or to seek any relief against Bayer under Count I. Bayer denies the remaining allegations.

656. Bayer denies the allegations in Paragraph 656.

657. Bayer denies the allegations in Paragraph 657.

658. Bayer denies the allegations in Paragraph 658.

659. Bayer denies the allegations in Paragraph 659.

660. Bayer denies the allegations in Paragraph 660.

UNNUMBERED “WHEREFORE” PARAGRAPH AND ITS SUBPARTS A-G:

Bayer denies the State is entitled to a judgment or any other relief requested in its prayer for relief and “Wherefore” Paragraph and its subparts A-G.

COUNT II

661. Bayer realleges and incorporates its responses to the allegations in Paragraphs 1 through 660.

662. Bayer admits that the State purports to bring this action and to seek relief under Count II as alleged but denies that the State is entitled to maintain this action or to seek any relief against Bayer under Count II. Bayer denies the remaining allegations.

663. Bayer denies the allegations in Paragraph 663.

664. Bayer denies the allegations in Paragraph 664.

665. Bayer denies the allegations in Paragraph 665.

666. Bayer denies the allegations in Paragraph 666.

667. Bayer denies the allegations in Paragraph 667.

UNNUMBERED “WHEREFORE” PARAGRAPH AND ITS SUBPARTS A-H:

Bayer denies the State is entitled to a judgment or any other relief requested in its prayer for relief and “Wherefore” Paragraph and its subparts A-H.

COUNT III

668. Bayer realleges and incorporates its responses to the allegations in Paragraphs 1 through 667.

669. Bayer admits that the State purports to bring this action and to seek relief under Count III as alleged but denies that the State is entitled to maintain this action or to seek any relief against Bayer under Count III. Bayer denies the remaining allegations.

670. To the extent the allegations relate to parties other than Bayer, Bayer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations and therefore denies them. To the extent the allegations pertain to Bayer, upon information and belief, Bayer admits that it is a manufacturer of drugs included in the Montana Medicaid drug formulary.

671 – 672 (a)-(c). Bayer admits that it has entered into certain rebate agreements pursuant to 42 U.S.C. § 1396r-8, which is the best evidence of its contents. To the extent the allegations state legal arguments or conclusions, no answer is required. To the extent the allegations refer to other parties or entities other than Bayer, Bayer lacks information or knowledge sufficient to form a belief as to the truth or falsity of those allegations and therefore denies them. To the extent the allegations refer to statutes, regulations or other documents, those documents are the best evidence of their contents and Bayer denies the State's characterization thereof. Bayer denies the remaining allegations that pertain to it.

673. To the extent the allegations relate to parties other than Bayer, Bayer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations

and therefore denies them. To the extent the allegations pertain to Bayer, upon information and belief, Bayer admits the allegations.

674/ Bayer denies the allegations in Paragraph 674.

675. Bayer denies the allegations in Paragraph 675.

676. Bayer denies the allegations in Paragraph 676.

677. Bayer denies the allegations in Paragraph 677.

678. Bayer denies the allegations in Paragraph 678.

679. Bayer denies the allegations in Paragraph 679.

UNNUMBERED “WHEREFORE” PARAGRAPH AND ITS SUBPARTS A-D:

Bayer denies the State is entitled to a judgment or any other relief requested in its prayer for relief and “Wherefore” Paragraph and its subparts A-D.

COUNT IV

680. Bayer realleges and incorporates its responses to the allegations in Paragraphs 1 through 679.

681. Bayer admits that the State purports to bring this action and to seek relief under Count IV as alleged but denies that the State is entitled to maintain this action or to seek any relief against Bayer under Count IV. Bayer denies the remaining allegations.

682. To the extent the allegations relate to parties other than Bayer, Bayer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations

and therefore denies them. To the extent the allegations pertain to Bayer, upon information and belief, Bayer admits that it is a manufacturer of drugs included in the Montana Medicaid drug formulary.

683 – 684 (a)-(c). Bayer admits that it has entered into certain rebate agreements pursuant to 42 U.S.C. § 1396r-8, which is the best evidence of its contents. To the extent the allegations state legal arguments or conclusions, no answer is required. To the extent the allegations refer to other parties or entities other than Bayer, Bayer lacks information or knowledge sufficient to form a belief as to the truth or falsity of those allegations and therefore denies them. To the extent the allegations refer to statutes, regulations or other documents, those documents are the best evidence of their contents and Bayer denies the State's characterization thereof. Bayer denies the remaining allegations that pertain to it.

685. To the extent the allegations relate to parties other than Bayer, Bayer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations and therefore denies them. To the extent the allegations pertain to Bayer, upon information and belief, Bayer admits the allegations.

686. Bayer denies the allegations in Paragraph 686.

687. Bayer denies the allegations in Paragraph 687.

688. Bayer denies the allegations in Paragraph 688.

689. Bayer denies the allegations in Paragraph 689.

690. Bayer denies the allegations in Paragraph 690.

691. Bayer denies the allegations in Paragraph 691.

UNNUMBERED “WHEREFORE” PARAGRAPH AND ITS SUBPARTS A-D:

Bayer denies the State is entitled to a judgment or any other relief requested in its prayer for relief and “Wherefore” Paragraph and its subparts A-D.

COUNT V

692. Bayer realleges and incorporates its responses to the allegations in Paragraphs 1 through 691.

693. Bayer denies the allegations in Paragraph 693.

UNNUMBERED “WHEREFORE” PARAGRAPH, ITS SUBPARTS A-C.

Bayer denies the State is entitled to a judgment or any other relief requested in its prayer for relief and “Wherefore” Paragraph and its subparts A-C.

SECTION TWELVE

UNNUMBERED DEMAND FOR JURY TRIAL PARAGRAPH. Bayer denies the State is entitled to any relief or to a jury trial.

DEFENSES

First Defense

The State fails to state a claim against Bayer upon which relief may be granted.

Second Defense

The State’s claims are barred, in whole or in part, because the State has released, settled, entered into an accord and satisfaction, and otherwise compromised its claims.

Third Defense

The State's claims are barred, in whole or in part, by the political question and separation of powers doctrines.

Fourth Defense

The State's claims are barred, in whole or in part, by the filed rate doctrine.

Fifth Defense

The State has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Bayer as alleged.

Sixth Defense

To the extent the State obtains recovery in any other case predicated on the same factual allegations, the State is barred from seeking recovery against Bayer pursuant to the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

Seventh Defense

The State's claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitution of the State of Montana and any other States whose laws are or become relevant in the course of this multidistrict litigation.

Eighth Defense

The State's claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by Bayer in judicial, legislative, or administrative proceedings of any kind or at any level of government.

Ninth Defense

Any and all actions taken by Bayer with respect to any of the matters alleged were taken in good faith and in accordance with established industry practice.

Tenth Defense

The State's state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

Eleventh Defense

The State's claims are preempted by the Commerce Clause of the United States Constitution.

Twelfth Defense

The State's claims against Bayer are barred because Bayer has complied with all applicable regulations of the federal and state governments.

Thirteenth Defense

The State's claims against Bayer are barred, in whole or in part, by the applicable statutes of limitations and repose and by the doctrines of laches, estoppel, and waiver.

Fourteenth Defense

The State's claims are barred, in whole or in part, because they violate Bayer's rights under the *Due Process* and *Ex Post Facto* clauses of the United States Constitution, as well as all applicable state constitutions, insofar as the State seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

Fifteenth Defense

The State's claims are barred because Bayer's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by the State.

Sixteenth Defense

The State fails to state with particularity facts to support the fraud allegations and to plead with particularity the fraudulent concealment and multi-source medicine allegations against Bayer.

Seventeenth Defense

The State's claims against Bayer are barred, in whole or in part, because Bayer did not make any false statements to the State or any of the citizens for whom the State is seeking relief. As to any statement asserted against Bayer that the State alleges to be false or misleading, Bayer had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

Eighteenth Defense

Bayer denies that the State has valid deceptive trade practices, consumer protection claims, or Medicaid fraud claims against Bayer under the laws of Montana or any other State whose law is or becomes relevant in the course of this multidistrict litigation. However, if such claims are found to exist, Bayer pleads all available defenses under the Acts.

Nineteenth Defense

Any allegedly fraudulent statements or conduct of Bayer did not directly or proximately cause the alleged injuries of the State as required under state deceptive trade practices or Medicaid fraud laws, including without limitation those of Montana.

Twentieth Defense

Bayer's conduct was neither "deceptive," "misleading," "unlawful," nor "illegal" as required under certain state deceptive trade practices or Medicaid fraud laws, including without limitation those of Montana.

Twenty-First Defense

To the extent that the State attempts to seek equitable relief against Bayer, it is not entitled to such relief because they have an adequate remedy at law.

Twenty-Second Defense

The State lacks standing to bring some or all of the claims in this suit, including but not limited to its asserted deceptive trade practices or Medicaid fraud claims against Bayer under certain state deceptive trade practices or Medicaid fraud laws.

Twenty-Third Defense

The State did not rely on the allegedly fraudulent statements or conduct of Bayer as required under certain state deceptive trade practices or Medicaid fraud laws, including without limitation those of Montana, New York and Pennsylvania.

Twenty-Fourth Defense

The State's claims against Bayer under the various state statutes are barred in whole or in part to the extent those statutes: (1) do not allow (or did not allow at the time the conduct was alleged herein) recovery of damages by indirect purchasers; and (2) do not govern conduct that is predominantly interstate in nature.

Twenty-Fifth Defense

To the extent the State seeks injunctive relief against Bayer, such claims were mooted by the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Twenty-Sixth Defense

To the extent the State seeks injunctive relief against Bayer, such claims are barred by the doctrines of *in pari delicto* and/or unclean hands.

Twenty-Seventh Defense

Any claims brought on behalf of third party payors against Bayer are barred, in whole or part, with respect to any alleged overcharge or on the ground that third party payors passed on any effect of the alleged inflated prices to their customers or employees in the form of higher premiums.

Twenty-Eighth Defense

The State's claims against Bayer are barred, in whole or in part, with respect to any alleged overcharge because such overcharge, if any, was absorbed, in whole or part, by a person and/or entity which purchased the medicine directly, and/or by an intermediate indirect purchaser, and was not passed on to the State.

Twenty-Ninth Defense

The State's claims against Bayer are barred, in whole or in part, due to its failure to join indispensable parties.

Thirtieth Defense

The State's claims against Bayer are barred, in whole or in part, because it has suffered no damages.

Thirty-First Defense

The State's claims are barred, in whole or in part, because any injuries sustained by the State were the result of intervening or superceding conduct of third parties.

Thirty-Second Defense

The State's claims are barred, in whole or in part, because any allegedly fraudulent statement or conduct of Bayer was not consumer-oriented as required under the Montana consumer protection laws.

Thirty-Third Defense

The State's claims are barred, in whole or in part, because some or all of the State's claims arise from its failure to follow its federal and state statutory and regulatory obligation to set reimbursement rates at Estimated Acquisition Cost.

Thirty-Fourth Defense

The State's claims against Bayer for damages are barred, in whole or in part: (1) because it failed to mitigate its damages, and its failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to Bayer; (2) because it would be unjustly enriched if allowed to recover; (3) by the doctrine of consent and/or ratification to the extent that the State has received and paid for medicines manufactured, marketed and sold by Bayer or its affiliates after the filing of the State's original Complaint; and (4) because any purported damages are speculative and remote and because of the impossibility of ascertaining and allocating the damages.

Thirty-Fifth Defense

Bayer is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by the State with respect to the same injuries.

Thirty-Sixth Defense

Any damages recovered by the State from Bayer must be limited by the applicable statutory ceilings on recoverable damages.

Thirty-Seventh Defense

The State fails to allege facts or a cause of action against Bayer sufficient to support a claim for attorneys' fees, treble damages, and/or legal fees.

Thirty-Eighth Defense

To the extent punitive damages are sought, the State's punitive damages claims against Bayer: (1) have no basis in law or fact; (2) are not recoverable because the allegations are legally insufficient to support a claim for punitive damages against Bayer; and (3) cannot be sustained because: (i) laws regarding the standards for determining liability for and the amount of punitive damages fail to give Bayer prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed and are void for vagueness in violation of Bayer's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the constitutions of any applicable states' laws; (ii) an award of punitive damages would violate Bayer's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law, statutes, and public policy of any applicable states' laws; (iii) an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against Bayer for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of Bayer's medicines would constitute impermissible multiple punishments for the same wrong, in violation of Bayer's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the constitutions, common law, and statutory law of any applicable states' laws; (iv) any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong

committed by each alleged tortfeasor, would violate Bayer's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law, and public policies of any applicable states' law; and (v) any award of punitive damages, which are penal in nature, without according Bayer the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Bayer's rights guaranteed by the Fourth, Fifth, and Sixth Amendments as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the constitutions, common law, and public policies of any applicable states' laws.

Thirty-Ninth Defense

To the extent punitive damages are sought, the State's claim for punitive damages against Bayer cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and corporate status of Bayer; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (5) is not properly instructed regarding The State's burden of proof with respect to each and every element of a claim for punitive damages; and (6) is not subject to trial court and appellate judicial review for

reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate Bayer's due process and equal protection rights guaranteed by the fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the constitutions, common law, and public policies of any applicable states' laws.

Fortieth Defense

To the extent punitive damages are sought, the State's claim for punitive damages against Bayer cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate Bayer's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate Bayer's right not to be subject to an excessive award; and (3) be improper under the constitutions, common law, and public policies of any applicable states' laws.

Forty-First Defense

Bayer adopts by reference any additional applicable defense pled by any other defendant not otherwise pled herein.

Forty-Second Defense

Bayer hereby gives notice that it intends to rely upon any additional defense that is now or may become available or appear during or as a result of the discovery proceedings in this action and hereby reserve its right to amend its answer to assert such defense. Bayer also reserves the right to assert such other and related defenses as may become available in the event of a determination that the action, or some part thereof, is governed by the substantive law of a state other than Montana, California, Delaware, Florida, Illinois, Louisiana, Minnesota, New

Jersey, New York, Pennsylvania, Texas, Washington, and/or any other State whose law is or becomes relevant in the course of this multidistrict litigation.

WHEREFORE, Bayer prays that this Court:

1. Dismiss the State of Montana's Second Amended Complaint with prejudice and enter judgment in its favor and against the State;
2. Award Bayer its costs and expenses; and
3. Grant such other and further relief as this Court deems just and proper.

BAYER CORPORATION

By: /s/ Robert Sherman
One of Bayer Corp.'s Attorneys

Robert P. Sherman
NIXON PEABODY
100 Summer Street
Boston, Massachusetts 02110
(617) 345-6188
FAX: (866) 382-6138

Richard D. Raskin
Michael P. Doss
Sara K. Rankin
SIDLEY AUSTIN BROWN & WOOD LLP
10 S. Dearborn Street
Chicago, Illinois 60603
(312) 853-7000
FAX: (312) 853-7036

ATTORNEYS FOR DEFENDANT BAYER
CORPORATION

July 12, 2004

CERTIFICATE OF SERVICE

I hereby certify that, on this 12th day of July, 2004, I have served a copy of the foregoing Defendant Bayer Corporation's Answer to the State of Montana's Second Amended Complaint on all counsel of record by electronic service pursuant to Case Management Order No. 2, by causing a copy to be sent to Verilaw Technologies for posting and notification.


